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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/444,284	11/19/1999	RONALD VOGELS	4231US	8464

7590 03/18/2004

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EXAMINER
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CHEN, SHIN LIN

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 03/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/444,284

Applicant(s)

VOGELS ET AL.

Examiner

Shin-Lin Chen

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,21,25,28-32,37,44,51,54,56-62,65,69 and 71 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 28-32 and 37 is/are allowed.
- 6) ☒ Claim(s) 2,21,25,44,51,54,56-62,65,69 and 71 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Upon further consideration of the present invention, the finality of the Official action mailed 11-20-03 has been withdrawn.

Applicants' amendment filed 2-9-04 has been entered. Claims 2, 25, 37, 44, 58, 60, 65, 69 and 71 have been amended. Claims 50, 64 and 70 have been canceled. Claims 2, 21, 25, 28-32, 37, 44, 51, 54, 56-62, 65, 69 and 71 are pending and under consideration.

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 2, 21, 25, 44, 51, 54, 56-62, 65, 69 and 71 are rejected under 35 U.S.C. 102(e) as being anticipated by Crystal et al., 2000 (US Patent 6,127,525).

Claims 2, 21, 25, 69 and 71 are directed to a recombinant adenovirus of a subgroup C origin, such as adenovirus type 5, or an adenovirus capsid having a reduced tissue tropism for liver cells as compared to corresponding wild type adenovirus, said recombinant adenovirus comprising a chimeric fiber protein having a knob domain of an adenovirus origin of adenovirus 12, 16, 28, or 40-L, and a composition comprising said recombinant adenovirus. Claims 44, 51, 54, and 56-62 and 65 are directed to a recombinant adenovirus of a subgroup C origin, such as adenovirus type 5, or an adenovirus capsid having a increased tropism for smooth muscle cells as

compared to adenovirus type 5 or corresponding wild type adenovirus, said recombinant adenovirus comprising a chimeric fiber protein having a knob domain of an adenovirus subgroup B origin, such as adenovirus 11, 16, 35 and 51. Claim 54 specifies that the adenoviral nucleic acid is modified to reduce or disable its replication ability in a target cell. Claims 56 and 57 specify the recombinant adenovirus further comprises at least one non-adenoviral nucleic acid incorporated within the genome. Claim 59 specifies the subgroup B adenovirus is adenovirus 16. Claim 60 specifies the remaining part of the chimeric fiber protein is of adenovirus subgroup C origin.

Crystal teaches preparation of a chimeric adenoviral coat protein, including a chimeric adenovirus hexon and/or fiber protein, comprising a nonnative amino acid sequence such that said chimeric adenoviral coat protein has decreased ability or inability to be recognized by a neutralizing antibody against the corresponding wild-type adenovirus coat protein (e.g. abstract, column 6). Crystal also teaches that a region of a wild-type adenovirus coat protein can be deleted and replaced with a spacer region comprising the corresponding coat protein region of another adenoviral serotype, and coat proteins of group B or C adenovirus can be used, which include Ad1, Ad2, Ad3, Ad5, Ad7, Ad11, Ad12, Ad14, Ad16, Ad21, Ad34, Ad35, Ad40, Ad41 and Ad48. For example, a region of an Ad2 coat protein can be replaced with the corresponding region of an Ad5 or Ad7 coat protein, and vice versa (e.g. column 4, lines 32-41, column 10, lines 41-67). Crystal teaches the adenoviral vector can be replication competent or can be modified to become replication deficient (e.g. column 15, lines 15-34). Further, a passenger gene, such as therapeutic gene or a reporter gene, can be employed in the vector and the adenovirus vector having the chimeric coat protein can be used for gene transfer in gene therapy

(e.g. column 17, 18). Knob domain is a part of the fiber protein. Exchange of the fiber protein can be any part of the said fiber protein, such as the knob protein. Further, the characteristics of reduced tissue tropism for liver cells and increased tropism for smooth muscle cells of the claimed recombinant adenovirus are inherent to the chimeric adenovirus taught by Crystal. Therefore, claims 2, 21, 25, 44, 51, 54, 56-62, 65, 69 and 71 are anticipated by Crystal.

It should be noted that the method claim 37 is free of prior art.

### ***Conclusion***

Claims 2, 21, 25, 44, 51, 54, 56-62, 65, 69 and 71 are rejected. Claims 28-32 and 37 are in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (571) 272-0726. The examiner can normally be reached on Monday to Friday from 9:30 am to 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for this group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Shin-Lin Chen, Ph.D.



**SHIN-LIN CHEN  
PRIMARY EXAMINER**